

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

In re AbbVie, Inc., et al.	)	
Coordinated Pretrial Proceedings	)	Case No. 14-cv-1748
	)	
This Document Relates to:	)	Honorable Matthew F. Kennelly
Case No. 14-cv-1483 (Cataudella);	)	
Case No. 14-cv-1298 (Lau); and	)	
Case No. 14-cv-2394 (Parker)	)	
	)	

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS ENDO  
PHARMACEUTICALS INC.'S, ELI LILLY AND COMPANY AND LILLY USA,  
LLC'S, AND AUXILIUM PHARMACEUTICALS, INC.'S MOTION TO JOIN AND  
SUPPLEMENT DEFENDANTS' MOTION TO DISMISS COMPLAINTS**

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## **PRELIMINARY STATEMENT**

Defendants Endo Pharmaceuticals Inc. (“Endo”), Eli Lilly and Company and Lilly USA, LLC (collectively “Lilly”), and Auxilium Pharmaceuticals, Inc. (“Auxilium”) join in Defendants’ Motion to Dismiss Complaints and the accompanying Memorandum of Law (“Defendants’ Memo”), and adopt and incorporate by reference the factual and legal arguments set forth therein. Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants Endo, Lilly, and Auxilium submit this Joinder and Supplement to assert additional legal and factual bases to dismiss the claims in Cataudella (against Endo), in Lau (against Lilly), and in Parker (against Auxilium).<sup>1</sup>

Not a single Plaintiff names Endo, Lilly, or Auxilium as the sole defendant in any of the 39 cases discussed in Defendants’ Motion to Dismiss. Of the 39 cases: (a) only Plaintiff Cataudella names Endo as a co-defendant; (b) only Plaintiff Lau names Lilly as a co-defendant; and (c) only Plaintiff Parker names Auxilium as a co-defendant. Endo, Lilly, and Auxilium submit this Supplement to Defendants’ Motion to Dismiss because Cataudella, Lau, and Parker each fails to plead specific facts related to Endo, Lilly, and Auxilium, or related to Plaintiffs’ use of these Defendants’ respective Testosterone Replacement Therapy (“TRT”) prescription medications. This Court should, therefore, dismiss Cataudella’s, Lau’s, and Parker’s Complaints because they have failed to meet the pleading requirements of Rules 8(a) and 9(b).

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<sup>1</sup> This Joinder and Supplement does not repeat the factual and legal arguments related to Rules 8(a) and 9(b), which Defendants raise in Defendants’ Motion to Dismiss and Defendants’ Memo, and incorporate here by reference.

## STATEMENT OF FACTS<sup>2</sup>

### A. Endo

#### 1. Cataudella's Specific Factual Allegations Regarding Endo or Fortesta.

“Defendant Endo Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.” Cataudella Compl. ¶ 9.<sup>3</sup> “The FDA approved Fortesta on December 9, 2010.” *Id.* ¶ 37. Fortesta is a hydroalcoholic gel containing testosterone, which is applied to the thighs and enters the body through transdermal absorption. *Id.* ¶ 38. “Plaintiff was prescribed Fortesta and used it as directed from March 2013 until August 2013.” *Id.* ¶ 54.

#### 2. Cataudella's Generic Factual Allegations that Mention Endo or Fortesta.

Cataudella also includes in his Complaint generic factual allegations that mention both Fortesta and AndroGel, without distinguishing between the two prescription medications. *See, e.g., id.* ¶ 43 (“AndroGel and Fortesta may produce undesirable side effects to patients who use the drugs, including but not limited to, myocardial infarction, stroke, blood clots and death.”); *see also id.* ¶ 1, 11, 14, 16, 43-45.

### B. Lilly

#### 1. Lau's Specific Factual Allegations Regarding Lilly or Axiron.

“Defendant Eli Lilly and Company is a corporation organized and existing under the laws of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.” Lau Compl. ¶ 9 “Defendant Lilly USA, Inc. is a limited liability company

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<sup>2</sup> This motion accepts as true all of the well-pleaded factual allegations in Plaintiffs' Complaints.

<sup>3</sup> References to “¶ \_\_” are to paragraphs of the respective Complaint, which are attached as Ex. A (Cataudella), Ex. B (Lau), and Ex. C (Parker). References to “Ex. \_\_” are to exhibits attached hereto.

operating as a wholly owned subsidiary of Defendant Eli Lilly and Company, with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.” *Id.* ¶ 10. Acrux Limited originally developed Axiron. In March of 2010, Acrux and Eli Lilly and Company entered into an exclusive worldwide license agreement for commercialization of Axiron. On November 14, 2012, Axiron received FDA Approval.” *Id.* ¶ 12. “The FDA approved Axiron on November 23, 2010.” *Id.* ¶ 39. “Axiron is applied to the underarms.” *Id.* ¶ 40. “Plaintiff was prescribed Axiron and used it as directed throughout the month of July 2011.” *Id.* ¶ 56. As a result of *Defendants* marketing campaign, “Androgel’s sales increase[ed] to over \$1.37 billion per year, and Axiron’s sales increas[ed] to over \$178.7 million per year.” *Id.* ¶¶ 4-5, 32.

**2. Lau’s Generic Factual Allegations that Mention Lilly or Axiron.**

Lau also includes in his Complaint generic factual allegations that mention both Axiron and AndroGel, without distinguishing between the two prescription medications. *See, e.g., id.* ¶ 16 (“This action is for damages brought on behalf of Plaintiff who was prescribed and supplied with, received, and who has taken and applied the prescription drugs Axiron and AndroGel as tested, studied, researched, evaluated, endorsed, designed, formulated....”); *see also id.* ¶¶ 1, 13, 16, 18, 40, 45-47.

**C. Auxilium**

**1. Parker’s Specific Factual Allegations Regarding Auxilium or Testim.**

“Defendant Auxilium Pharmaceuticals, Inc. is a Delaware corporation which has its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087.” Parker Compl. ¶ 11. “The Food and Drug Administration approved Testim on October 31, 2002 for the treatment of adult males who have low or no testosterone. After FDA approval, Testim was widely advertised and marketed by Defendant Auxilium Pharmaceuticals, Inc. as a safe and effective testosterone replacement therapy.” *Id.* ¶ 39. Testim is a hydroalcoholic gel containing

testosterone, which is applied to the shoulders and upper arms and enters the body through transdermal absorption. *Id.* ¶ 40. As a result of **Defendants** marketing campaign, “Androgel’s sales increase[ed] to over \$1.37 billion per year, and Testim’s sales increas[ed] to over \$209 million per year.” *Id.* ¶¶ 4-5.

## **2. Parker’s Generic Factual Allegations that Mention Auxilium or Testim.**

Parker also includes in his Complaint generic factual allegations that mention both Testim and AndroGel, without distinguishing between the two prescription medications. *See, e.g., id.* ¶ 56 (“Plaintiff Loran Parker used AndroGel and Testim for symptoms he attributed to low testosterone as a result of Defendants’ advertisements.”); *see also id.* ¶¶ 1, 14, 16, 45-47, 56-57.

## **D. Cataudella, Lau, and Parker Each Are Missing Key Specific Factual Allegations in Their Complaints.**

Cataudella’s, Lau’s, and Parker’s Complaints each fails to allege whether the respective Plaintiff took AndroGel at the same time as taking Fortesta (Cataudella Compl. ¶ 54), Axiron (Lau Compl. ¶ 56), or Testim (Parker Compl. ¶ 56). Parker does not even allege the time frame of when he started or stopped taking Testim. Parker Compl. ¶¶ 56-57. Cataudella’s, Lau’s, and Parker’s Complaints also do not contain any allegations about specific risk factors associated with TRT use generally, or claim that Cataudella, Lau, or Parker experienced any such risk factors due to his use of Fortesta, Axiron, or Testim specifically, such as allegedly increased levels of hematocrit or hemoglobin, which in turn increase the risk of heart attack. *See* Cataudella Compl. ¶¶ 34-36; *see* Lau Compl. ¶¶ 36-38; *see* Parker Compl. ¶¶ 34-36.

Without distinguishing among AbbVie and Abbott, and their co-defendants (Endo, Lilly, or Auxilium), Cataudella, Lau, and Parker allege simply that “**Defendants** successfully marketed testosterone by undertaking a ‘disease awareness’ marketing campaign” to

encourage consumers' use of testosterone therapy, even though they knew it was not safe. Cataudella Compl. ¶¶ 48-49 (emphasis added); Lau Compl. ¶¶ 50-51 (emphasis added); Parker Compl. ¶¶ 50-51 (emphasis added). None of these three Plaintiffs identify a single specific piece of marketing literature that he or his doctor saw. Nor do any of them identify any television, print, or online advertising by Endo, Lilly, or Auxilium. *See* Cataudella Compl. ¶¶ 24, 52; *see* Lau Comp. ¶¶ 26, 54; *see* Parker Compl. ¶¶ 24, 54.

Although Cataudella alleges he “was prescribed” “and used” Fortesta (Cataudella Compl. ¶ 54), Lau alleges he “was prescribed” “and used” Axiron (Lau Compl. ¶ 56), and Parker alleges he “was prescribed and supplied with” Testim (Parker Compl. ¶¶ 14, 56), each of these Plaintiffs fails to identify his prescribing doctor. Cataudella, Lau, and Parker also each fail to allege any facts that connect any conduct by Endo, Lilly, or Auxilium, respectively, to his physician or to his physician's decision to prescribe Fortesta (to Cataudella), Axiron (to Lau), or Testim (to Parker). This is especially significant because Fortesta's, Axiron's, and Testim's prescribing information each instruct physicians to monitor hemoglobin and hematocrit levels in patients.<sup>4</sup> Plaintiffs' Complaints lack critical allegations that could plausibly support their claims against these respective Defendants. *See also* Defendants' Memo.

## ARGUMENT

### **I. The Court Should Dismiss All of Cataudella's, Lau's, and Parker's Claims Against Endo, Lilly, and Auxilium Under Rule 8(a).**

Cataudella, Lau, and Parker fail to allege specific facts against each Defendant — Endo, Lilly, and Auxilium — to support any of their six causes of action<sup>5</sup> and therefore this

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<sup>4</sup> *See* Ex. 5 to Defendants' Memo for Defendants' respective prescribing information.

<sup>5</sup> The six causes of action are Strict Liability — Failure to Warn (First Cause of Action), Negligence (Second Cause of Action), Breach of Implied Warranty (Third Cause of Action),  
(continued...)



Court should dismiss their claims against these Defendants. “To survive a motion to dismiss,” Rule 8(a)(2) requires a complaint to contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Aschcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). Mere legal conclusions are “not entitled to the assumption of truth.” *Id.* at 679.

Here, Cataudella, Lau, and Parker fail to provide any factual content that allows the Court to draw a reasonable inference that Endo, Lilly, and Auxilium are liable for any alleged misconduct. Cataudella, for example, only pleads *four* specific facts about Endo and Fortesta: (1) Endo’s principal place of business (Cataudella Compl. ¶ 9); (2) when the FDA approved Fortesta (*id.* ¶ 37); (3) that Fortesta is a hydroalcoholic testosterone gel that is applied to the thighs and enters the body through transdermal absorption (*id.* ¶ 38); and (4) a statement that Cataudella was prescribed Fortesta and used it as directed from March 2013 until August 2013 (*id.* ¶ 54). The specific facts that Lau pleads against Lilly (*see* Lau Compl. ¶¶ 4-5, 9-10, 12, 32, 39-40, 56) and that Parker pleads against Auxilium (*see* Parker Compl. ¶¶ 4-5, 11, 39-40) are equally lacking.

In sum, each Plaintiff does nothing more in his Complaint than allege, in an entirely conclusory fashion, that he took Fortesta (Cataudella), Axiron (Lau), or Testim (Parker) and that he later suffered an alleged injury. Because Cataudella, Lau, and Parker merely recite the elements of the causes of action, without stating any specific claims against these particular

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Breach of Express Warranty (Fourth Cause of Action), Fraud (Fifth Cause of Action), and Negligent Misrepresentation (Sixth Cause of Action).

Defendants, the Court should dismiss their claims against these Defendants pursuant to Rule 8(a), *Iqbal*, and *Twombly*. See also *Adams v. City of Indianapolis*, 742 F.3d 720, 728 (7th Cir. 2014); *Dura Pharms. v. Broudo*, 544 U.S. 336, 346-47 (2005); *Kwasniewski v. Sanofi-Aventis U.S., LLC*, 2:12-CV-00515-GMN-NJK, 2013 WL 2558283, at \*2 (D. Nev. June 8, 2013) (dismissing complaint where the plaintiff’s cursory allegations that he took a medication and suffered injury were “conclusory and not entitled to the presumption of truth”).

Moreover, a review of Cataudella’s, Lau’s, and Parker’s Complaints proves that their general claims against “Defendants” are not directed at Endo, Lilly, or Auxilium. For example, Cataudella pleads that “Defendants’ marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users....” Cataudella Compl. ¶ 47. However, Cataudella also pleads that “[t]he FDA approved Fortesta on December 9, 2010.” *Id.* ¶ 37. Cataudella has not (and cannot) plead any facts that make it “plausible” that Endo engaged in an aggressive marketing campaign for Fortesta a decade before the FDA approved Fortesta. The same inconsistency is true for Lau’s claims against Lilly. Compare Lau Compl. ¶ 49 (“Defendants’ marketing strategy beginning in 2000 has been to aggressively market and sell their products....”); with *id.* ¶ 39 (“The FDA approved Axiron on November 23, 2010.”) Similarly, in Parker, the Complaint refers generally to “television advertisements” and “Defendants’ marketing strategy,” but Parker’s only specific references are to advertisements by AbbVie. See, e.g., Parker Compl. ¶¶ 24, 29, 49. Thus, Cataudella’s, Lau’s, and Parker’s Complaints fail to state a claim for relief “that is plausible on its face” or that allows this Court to draw a reasonable inference that Endo, Lilly, and Auxilium are liable for the misconduct alleged — as Rule 8(a), *Iqbal*, and *Twombly* require.

## **II. The Court Should Dismiss Cataudella's, Lau's, and Parker's Fraud and Negligent Misrepresentation Claims Against Endo, Lilly, and Auxilium Under Rule 9(b).**

### **A. Cataudella, Lau, and Parker Fail to Allege Any Specific Facts Against Endo, Lilly, or Auxilium.**

Rule 9(b) requires a plaintiff to plead with particularity for each defendant, “the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff.” *Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990); *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., Inc.*, 536 F.3d 663, 668 (7th Cir. 2008). Each Plaintiff’s misrepresentation claim, while “not by definition [a] fraudulent tort[],” must still conform to Rule 9(b) because it is “premised upon a course of fraudulent conduct.” *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007); *see also, SFRL Inc. v. Galena State Bank & Trust Co.*, No. 11 C 50277, 2012 WL 2839814, at \*2 (N.D. Ill. July 10, 2012) (applying Rule 9(b) to negligent misrepresentation claim). “Rule 9(b) applies to ‘averments of fraud,’ not claims of fraud, so whether the rule applies will depend on the plaintiffs’ factual allegations.” *Borsellino*, 477 F.3d at 507.

As a threshold matter, Cataudella, Lau, and Parker fail to identify any particular misstatement or omission by Endo, Lilly, or Auxilium to support their fraud and negligent misrepresentation claims. Specifically, none of the three Plaintiffs allege that they<sup>6</sup> or their prescribing physicians, saw or relied upon any piece of advertising by Endo, Lilly, or Auxilium.

Viewed through the prism of Rule 9(b), Plaintiffs’ respective Complaints also fail to allege any specific facts related to any alleged misrepresentation or omission by Endo, Lilly,

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<sup>6</sup> As discussed in Defendants’ Memo (at pp. 3-4, 24-25) and the attached Appendix B, under the learned intermediary doctrine, Defendants only had a duty to warn Plaintiffs’ doctors, not Plaintiffs.

or Auxilium, including: (1) the identity of the employee or agent who made the alleged misrepresentation or omission; (2) the time when the alleged misrepresentation or omission was made; (3) the place where it was made; (4) the content, or lack thereof; (5) the method used to communicate; and (6) whether any alleged misrepresentation or omission was made to Plaintiff or one of Plaintiffs' prescribing physicians. Thus, the Court should dismiss Plaintiffs' fraud and negligent misrepresentation claims for failing to meet Rule 9(b)'s heightened pleading standard.

**B. Cataudella's, Lau's, and Parker's Allegations about "Defendants" Fail To Satisfy Rule 9(b).**

Under Rule 9(b), a plaintiff is prohibited from lumping all defendants together to support his fraud and negligent misrepresentation claims. *See Bank of America, N.A. v. Knight*, 875 F. Supp. 2d 837, 851 (N.D. Ill. 2012) (dismissing complaint and stating "[d]espite its unwieldy length, however, the complaint falls woefully short of complying with the mandates of Rule 9(b). It lumps all of the defendants together, never describing which defendant is responsible for what conduct or when each defendant participated in that unspecified conduct.").

Nonetheless, Cataudella, Lau, and Parker ignore Rule 9(b) and Northern District of Illinois precedent. Cataudella, Lau, and Parker attempt to plead around the absence of any specific allegations of fraud and negligent misrepresentations regarding Endo, Lilly, and Auxilium by lumping them together with Defendant AbbVie in order to make generic, vague and conclusory, fraud and negligent misrepresentation claims. *See, e.g.*, Cataudella Compl. ¶ 80 ("Defendants conducted a sales and marketing campaign to promote the sale of testosterone and willfully deceive Plaintiff...."); *see also* Lau Compl. at ¶ 82; Parker Compl. at ¶ 85. Cataudella's, Lau's, and Parker's generic claims aimed at "Defendants" do not satisfy Rule 9(b)'s heightened pleading requirement, and thus the Court should dismiss Cataudella's, Lau's, and Parker's fraud and negligent misrepresentation claims.

### **III. Plaintiffs' Home State's Law Also Bars Some of Cataudella's, Lau's, and Parker's Claims.**

For the reasons stated in Defendants' Memo, certain causes of action brought by Cataudella, Lau, and Parker should be dismissed under the individual Plaintiff's home state's law — as set forth below:

**Breach of Implied Warranty (Third Cause of Action):** For Arizona, *see* Defendants' Memo at p. 42 (Cataudella's claims against Endo); for Florida, *see id.* at pp. 40-41 (Lau's claims against Lilly); and for Nevada, *see id.* at p. 30 (Parker's claims against Auxilium).

**Breach of Express Warranty (Fourth Cause of Action):** For Arizona, *see* Defendants' Memo at pp. 29-30 and Appendix C (Cataudella's claims against Endo); for Florida, *see id.* at pp. 29-30, 40-41 and Appendix C (Lau's claims against Lilly); and for Nevada, *see id.* at p. 29-30 and Appendix B (Parker's claims against Auxilium).

**Negligent Representation (Sixth Cause of Action):** For Nevada, *see* Defendants' Memo at p. 43-44 (Parker's claims against Auxilium).

### **CONCLUSION**

For the reasons set forth above, the Court should dismiss the claims in Cataudella (against Endo), in Lau (against Lilly), and in Parker (against Auxilium) under Rules 8(a) and 9(b). The Court should also dismiss Cataudella's express and implied warranty claims pursuant to Arizona law, Lau's express and implied warranty claims pursuant to Florida law, and Parker's express and implied warranty and negligent representation claims pursuant to Nevada law.

Dated: June 4, 2014

Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

I, Andrew K. Solow, an attorney, hereby certify that on June 4, 2014, I caused a copy of the foregoing document to be filed via the Court's CM/ECF system, which will automatically serve and send e-mail notification of such filing to all registered attorneys of record.

/s/ Andrew K. Solow